

REMARKS

Specification

The Applicants have removed all known embedded hyperlinks and other browser-executable code from all instances in the specification, as requested by the Examiner.

Compliance with Sequence Rules and Drawing Changes

The Applicants thank the Examiner for his diligence in noticing the apparent error in labeling some of the sequences on pages 4 and 5 of Figure 3. The sequences on pages 4 and 5 of Figure No: 3 are fragments of SEQ ID NO: 3, and thus Applicants are not required to provide separate sequence identification numbers for the sequences. However, the sequence residue numbers are confusing. Consequently, Figure 3, Pages 4 and 5 have been amended to include the residue numbers of has SEQ ID NO: 3, and Applicants request acceptance of the Drawings under 37 C.F.R. 1.84.

Therefore, the Applicants believe that the concerns of the Examiner have been addressed and request the Examiner withdraw the requirement for the Applicants to provide SEQ ID NOs for said sequences.

Claim Objections

The Examiner has objected to claims 8, 9 and 27-29 for failing to further limit the subject matter of a previous claim. The Examiner based his objection upon the wording of claim 4 which recites the transitional phrase “consisting of,” and the Examiner’s contention that the wording of claims 8, 9, and 27-29 that includes the phrase “comprising” broadens the dependent claims, and thus the dependent claims do not further limit claim 4. The Applicants have amended claim 4, and thus request that the Examiner withdraw the objection of claims 8, 9, 27-29.

Claim Rejections under 35 U.S.C. § 101

The Examiner has rejected claims 4, 8, 9, 24 and 27-30 under 35 U.S.C. 101 because the Examiner asserts that the claimed invention is not supported by either an asserted utility which is specific and substantial, or a well-established utility. The

Examiner states that “CYP2D6 is known to act on a variety of drugs (listed on page 16), but the specification fails to positively identify any substrate of SEQ ID NO: 2, or to assert that any particular substrate is acted on by SEQ ID NO: 2.” The Examiner continues that “further experimentation would be required to determine what is the activity of SEQ ID NO: 2, i.e., on what drugs it will act.” Additionally, the Examiner asserts that the “specification does not establish any nexus between SEQ ID NOS:1-3 and any disease such that one of skill in the art could immediately use SEQ ID NOS:1-3 to develop therapy for any disease or disorder.” The Examiner then concludes that:

The use of nucleic acids for expression of SEQ ID NO: 2 is not a substantial utility according to the Guidelines for Examination of Applications for Compliance With the Utility Requirement because one would have to determine the function of SEQ ID NO: 2, or establish a relationship to some disease or disorder, in order to determine its real world use, if any.

The Examiner further states that because of a P34S substitution, a deletion of amino acids 118-168 and M374V and T486S substitutions in SEQ ID NO: 2 over the known CYP2D6 protein, that “the scope of substrates accepted by CYP2D6 varies with the allele or ortholog under consideration, and that the effects of sequence changes on CYP2D6 are unpredictable in terms of substrate specificity.” The Examiner then cites Lewis *et al.* (*Xenobiotica* 27(4):319-340, 1997), Yu *et al.* (*J. Pharm. Exp. Therap.* 303(3):1209-1300, 2002), Ellis *et al.* (*Biochem. J.* 345:565-571, 2000), DeGroot *et al.* (*Chem. Res. Toxicol.* 9:1079-1091, 1996) to provide support for his contention that “one of skill in the art would have had to empirically determine if the SEQ ID NO: 2 retained any activity at all, and if it did, on which substrates it would act. In other words, further research would be required to determine the real world use of the invention.” (see page 7 of the Action). For example, the Examiner cites Ellis *et al.* that describes CYP2D6 residues 118-122 that were predicted to interact with substrates, which the Examiner states as being missing from SEQ ID NO: 2 “as they fall within the deleted region (CYP2D6 118-168),” and “the entire predicted C-helix, containing the conserved WXXXR motif is absent from SEQ ID NO: 2.” (see page 6 of the Action)

The Examiner did not include claims 25 and 26 in the rejection, because “they have been interpreted to embrace isolated polynucleotides that have a well established utility. See rejections under 35 U.S.C. 102 below.”

The Applicants respectfully traverse the rejection based upon the following remarks.

Regarding the statement by the Examiner that the scope of substrates accepted by CYP2D6 varies with the allele or ortholog, and citing Lewis *et al.* (*Xenobiotica*, *Ibid*) as stating differences in substrate specificities among varying species, Lewis *et al.* also states that approximately 30% of drugs in current clinical use are metabolized by CYP2D6 (see paragraph 1 of the Introduction, for example). DeGroot *et al.* (*Chem. Res. Toxicol.*, *Ibid*) states in the abstract that “[a]ll drugs metabolized by P450 2D6 contain a basic nitrogen atom, and a flat hydrophilic region coplanar to the oxidation site which is either 5 or 7 Å away from the basic nitrogen atom.” DeGroot *et al.* also teaches that CYP2D6 is absent in 5-9% of the Caucasian population and results in a deficiency in drug oxidation of numerous drugs (see paragraph 1 of the Introduction, for example), and as a result, normal dosages administered clinically can be toxic to patients with an absence of CYP2D6. Therefore, the art cited by the Examiner provides support for utility contrary to the assertions of the Examiner. One of skill in the art would easily be able to determine whether or not a drug or compound is capable of serving as a substrate, based upon the structure provided by DeGroot, *et al.* Furthermore, Lewis *et al.* teaches that a large percentage (~30%) of currently-used drugs are metabolized by CYP2D6. Given the statement by DeGroot *et al.* that 5-9% of the Caucasian population have missing or mutated CYP2D6, then a utility for the present invention is clearly presented by the Applicants in the specification. Page 3, lines 13-24 and page 5, lines 3-8 of the specification outlines a utility of genotyping an individual to predict possible drug metabolizing problems in patients. A utility of screening patients to predict the presence or absent of CYP2D6 prior to therapy would render the question of substrate specificity moot, as a screening assay, such as one disclosed on page 39 of the specification can be used to identify patients who may have trouble metabolizing a given agent.

Regarding the assertion of the Examiner that Ellis *et al.* (*Biochem. J.*, *Ibid*) reports that predictions of substrate activity based on models should be tested empirically

contrasts with his following assertion that a 51 amino acid deletion would alter activity based upon a bacterial crystal structure reported by DeGroot *et al.* that amino acid 118-122 of CYP2D6 were critical for activity (see page 7 of the Action mailed July 29, 2004). DeGroot *et al.* stated that 20 amino acids appear to be important to binding protein. Of these 20, only 4 were identified by the Examiner as being absent. DeGroot *et al.* stated that not all of these amino acids were found to interact with the various ligands and identified the Asp³⁰¹ as belonging to one of the most active areas (see page 1089, col. 2, first(partial) paragraph. Regarding the Examiner's assertion that the "entire predicted C-helix" is not present (DeGroot, page 1081, Figure 1), Applicants request Examiner provide evidence that the C-helix is not present. Even if, *in arguendo*, the C-helix is not present, the Applicants still maintain that a specific utility of the present invention has been established by the Applicants, for screening of the presence or absence of CYP2D6 or mutated forms thereof; rendering a discussion of the activity of the polypeptide of the present invention moot. Therefore, the Applicants request that the Examiner withdraw the rejection under 35 U.S.C. § 101.

Claim Rejection Under 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected claims 4, 8, 9, 24 and 27-30 as being indefinite. The Applicants have amended claim 4 to remove the period after part (c) and to substitute a ";;" thereof. Applicants have amended claim 24 to remove the word "peptide" and substituted the word "polypeptide" thereof. Applicants believe that the amendments address the concerns of the Examiner and respectfully request that the rejection be withdrawn.

Claim Rejection Under 35 U.S.C. § 112, First Paragraph

The Examiner has rejected claims 4, 8, 9, 24 and 27-30 as "failing to comply with the enablement requirement." The Examiner substantially repeated many of the same arguments as set forth in the rejection under 35 U.S.C. 101, *supra*. In addition to citing factors as set forth in *In re Wands* (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)), the Examiner states that one of skill in the art could not have accurately predicted the effect of a deletion of 51 amino acids among other differences between the

present invention and the known protein. Most of the assertions by the Examiner have been addressed by the Applicants under 35 U.S.C. 101, *supra*. Regarding the statement by the Examiner that one of skill in the art would not be able to determine a substrate for the present invention, DeGroot *et al.* (*Chem. Res. Toxicol.*, *Ibid*) states in the abstract that “[a]ll drugs metabolized by P450 2D6 contain a basic nitrogen atom, and a flat hydrophilic region coplanar to the oxidation site which is either 5 or 7 Å away from the basic nitrogen atom.” DeGroot *et al.* also teaches that CYP2D6 is absent in 5-9% of the Caucasian population and results in a deficiency in drug oxidation of numerous drugs (see paragraph 1 of the Introduction, for example). Therefore, the art cited by the Examiner provides support for enablement contrary to the assertions of the Examiner. One of skill in the art would easily be able to determine whether or not a drug or compound is capable of serving as a substrate, based upon the structure provided by DeGroot, *et al.*

In regard to Examiner’s assertions that one of skill in the art would not be able to determine if the polypeptide of the present invention retained activity, the use of the polypeptide of the present invention to screening patients to predict the presence or absent of CYP2D6 prior to therapy would render the question of substrate specificity moot, as a screening assay, such as one disclosed on page 39 of the specification can be used to identify patients who may have trouble metabolizing a given agent. Regarding the assertion of the Examiner that Ellis *et al.* (*Biochem. J.*, *Ibid*) reports that predictions of substrate activity based on models should be tested empirically contrasts with his following assertion that a 51 amino acid deletion would alter activity based upon a bacterial crystal structure reported by DeGroot *et al.* that amino acid 118-122 of CYP2D6 were critical for activity (see page 7 of the Action mailed July 29, 2004). DeGroot *et al.* stated that 20 amino acids appear to be important to binding protein. Of these 20, only 4 were identified by the Examiner as being absent. DeGroot *et al.* stated that not all of these amino acids were found to interact with the various ligands and identified the Asp³⁰¹ as belonging to one of the most active areas (see page 1089, col. 2, first(partial) paragraph). Regarding the Examiner’s assertion that the “entire predicted C-helix” is not present (DeGroot, page 1081, Figure 1), Applicants request Examiner provide evidence that the C-helix is not present. Even if, *in arguendo*, the C-helix is not present, the

Applicants still maintain that enablement of the present invention has been established by the Applicants. The teachings of the cited references provide ample evidence that one of skill in the art would be able to use the claimed invention and that the state of the art and the disclosure provided in the present specification provided reasonable expectation of success at the time the invention was made. Therefore, the Applicants request that the Examiner withdraw the rejection under 35 U.S.C. § 112, first paragraph.

Rejection under 35 U.S.C. § 102(b)

Claims 25 and 26 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Brennan (US Patent No. 5,474,796). According to the Examiner, Brennan teaches “every conceivable 10mer oligonucleotide sequence.” The Examiner has interpreted claims 25 and 26 to mean “any nucleotide sequence” and thus asserts that the ‘796 patent anticipates the present invention. The Applicants traverse the rejection based upon the following arguments. A reasonable interpretation of the claimed invention *clearly* does not include the 10mers of the ‘796 patent, particularly in light of the transitional phrase “consisting of” in the claim. Nonetheless, the Applicants have amended claims 25 and 26 as suggested by the Examiner.

In regard to the Examiner’s statement that a new grounds of rejection would be required upon amending the claims to substitute “the” for “a,” the Applicants’ arguments as set forth under 35 U.S.C. §§ 101 and 112, first paragraph, *supra*, would also apply to claims 25 and 26, should the Examiner intend to include them in a future “new grounds for rejection.” Therefore, should the Examiner decide to include claims 25 and 26 in a future rejection under 35 U.S.C. §§ 101 and 112, first paragraph, the Applicants respectfully request that the Examiner consider the Applicants’ arguments as set forth *supra*, as they apply to claims 25 and 26, in the interest of “compact prosecution,” and thus, to expedite prosecution. In light of this request, if Examiner imposes additional reasons to reject claims 25 and 26, the Applicants request that any subsequent action based upon such new grounds as non-final, to give the Applicants an opportunity to fully address the concerns of the Examiner.

CONCLUSION

Claims 4, 8, 9, and 24-30 are under consideration by the Examiner. In view of the above remarks, Applicants respectfully submit that the application and claims are in condition for allowance, and request that the Examiner reconsider and withdraw the objections and rejections. If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is invited to call the undersigned agent should the Examiner believe a telephone interview would advance prosecution of the application.

Support for the amendments to the specification, claims and Figures can be found at least in the originally-filed claims and Figures 1-3. The amendment to the specification merely removed prohibited browser executable hyperlinks. The amendment to claims 4 and 24-26 are merely a rewording of the claims to enhance clarity and/or to correct typographical errors (e.g., claim 4(c)). Thus, the amendments to the specification, claims and Figures add no new subject matter and their entry is respectfully requested.

Applicants believe that the application is in condition for allowance.

Respectfully submitted,

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Annotated Sheet Showing Changes
09/820,788

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09/820,788

Intron: 3134-3903
Exon: 3904-4064
Intron: 4065-4496
Exon: 4497-4673
Intron: 4674-4865
Exon: 4866-5007
Intron: 5008-5201
Exon: 5202-5389
Intron: 5390-5843
Exon: 5844-5985
Intron: 5986-9556
Exon: 9557-9732
Stop 9733

SNPs:

DNA Position	Major	Minor	Domain	Protein Position	Major	Minor
3101	C	T A	Exon	107	T	T T
3439	A	G	Intron			
4908	C	T	Exon	245	P	L
5627	G	A	Intron			
6733	T	C	Intron			
7788	-	C T	Intron			
7867	G	A	Intron			
7948	C	T	Intron			

Context:

DNA
Position

3101 GTGTGACCCCCACCCCTGCCCCACGATCAGGAGGCTGGGTCTCCTCCTCCACCTGCTCA
CTCCTGGTAGCCCCGGGGGTCTGCCAAGGTTCAAATAGGACTAGGACCTGTAGTCTGGGG
TGATCCTGGCTTGACAAGAGGCCCTGACCCTCCCTCTGCAGTTGCGGCGCCGCTTCGGGG
ACGTGTTTAGCCTGCAGCTGGCCTGGACGCCGCTGGTCTGCTCAATGGGCTGGCGGCCG
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[C, T, A]
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ACCCGCCAGAAGCCCGGTGGGCGAGGCTGATGCGTCGAAGTGGCGGTGGCGGGGACCGCG
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3439 CGGCGGTGGGGGACAGAGACCGCGTTCCTGGGGCCCCGGGTGGACAGTGACCGTAGCCC
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GGCTGAGGACAGTGGGCCAGGAAACACCTGCACGGGGGAGGTGCGAGTCTGTGGGCTGG
GAGGGGGCGGGGCTACTGCCAGACCCGCCAGAAGCCCGGTGGGCGAGGCTGATGCGTCTG
AAGTGCGGTGGCGGGGACCGCGCTATGCTGCGGGCTCAGTGTGGGCGGGACGGGCGGG
[A, G]
TCTTCCTTGAGTGAAAGGTGGTCAGGGTGGGCGAGAGACGAGGTGGGGCCAAACCCGCC
CCAGGCAGGGGAGCAATGTGGGTGAGCAAAGAGTGGGCCCTGTGCCAGCTGGACCGGGC
TAGGGACTGCGGGAGACCTTGTGGAGCGCCAGGGTTGGAGTGGGTGGCGGAGGGTGGGGC
CAAGGCCTTATGGCAACGCCACGTGTCCGTCCCGCCCCAGGGGTGATCCTGTTCGGC
TATGGGCCCGCTGGCGCGAGCAGAGGCGCTTCTCCGTGTCCACCTTGCGCAACTTGGGC
(nt 3139-3739 of SEQ ID NO: 3)

4908 ATGACCTGGGACCCAGCCAGCCACCCGAGACCTGACTGAGGCCTTCCTGGCAAAGAAG
GAGAAGGTGAGAGTGGCTGCCACGGTGGGGGGCAAGGGTGGTGGGTGAAAGTCCCAGGA
GGAATGAGGGGAGGCTGGGCAAAAGGTTGGACAGTGCATACCCGGCGAGCCGCATCTG
GGCTGACAGGTGCAGAATTGAGGTCATTTGGGGGTACCCCGTTCTATCCCTGAGTAT
CCTCTCGGCCCTGCTCAGGCCAAGGGGAGCCCTGAGAGCAGCTTCAATGATGAGAACCTG
[C, T]
GCATAGTGGTGGGTAACTGTTCCTTGCCGGGATGGTGACCACCTCGACCACGCTGGCCT
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GGCAGGACTGAGGGAGGAAGGGTACAGCTGGGGGGCCCTGGGCTTAGCTGGGACACCCG
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(nt 4608-5208 of SEQ ID NO: 3)

Annotated Sheet Showing Changes
09/820,788

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[G,A]
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[T,C]
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(nt 6433-7033 of SEQ ID NO: 3)

7788 TCCAGTCCCCACTAGATTAGCTAGATAGAGTAGACAGAGAGCACTGATTGGTGGCTTTA
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[-,C,T]
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(nt 7488-8088 of SEQ ID NO: 3)

7867 AGGGTGTGACTGGTGTGTTTACAAACCTTGAGCTAGACACAGAGTGTGATTGGTGTAT
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[G,A]
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(nt 7567-8167 of SEQ ID NO: 3)

7948 TAAAGTTCCCCAAGTCCCCACCAGATTAGCTAGATAGAGTGTGTAATTGGTGCATGCACG
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CTTGGGCAGTGGACGGGACCAGGTGCCGTGGAGCAGTGGGAGGCACCCATCCGGGAGGCT
[C,T]
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CCTCACTGCCTGGGGCCAGAGGCACCAGCCGGCCGCTCCGAGTGCAGGGCCCGCTGAGCC
CCTGCCACCCAGAACTGGTGTGCCCCGCGAGCAACCCAGGTTCCCGCACACGCCTCTC
(nt 7648-8248 of SEQ ID NO: 3)

Chromosome mapping:
Chromosome #22